DEPARTMENT OF VETERANS AFFAIRS
Justification and Approval
For
Other Than Full and Open Competition

1. Contracting Activity:

Department of Veterans Affairs, Network Contracting Office (V18 NCO), in support of the VA Southwest Health Care Network (VISN 18.)
2237#: 544-12-1-036-0029, 644-12-1-034-0022, 678-12-2-053-0231

2. Nature and/or Description of the Action Being Processed:

This Justification for Other than Full and Open Competition comes as a result of a new requirement for a firm fixed priced contract/order to acquire laboratory testing services to Genomic Health Inc. , 301 Penobscot Dr. Redwood City, CA 94063-4700 for Oncotype DX tests.

The contract type will be a firm fixed price, Indefinite Delivery Contract-Requirements type contract for a base year plus three option years. Only three option years was selected because technology changes rapidly and market research will be conducted on a continual basis for any new technologies that will provide the best value and the most benefit to the Veterans and VA Southwest Health Care Network's Laboratory Departments. The estimated award date is January 13, 2012.

3. Description of Supplies/Services Required to Meet the Agency's Needs:

The use of the Oncotype DX test is a recommendation by the National Comprehensive Cancer Network (NCCN) that is followed by our Hematologists and Oncologists. This test aids in determining the next step to take in the treatment and prognosis of patients diagnosed with early stage I or stage II, node negative, estrogen receptor-positive invasive breast cancer. If this testing is not provided, our patients will be at higher risk of recurring cancer, which will have a negative impact on patient care.

	Total Est. Tests	Estimated cost per test	Est amount
Base Year Date of Award-12-31-2012	30	[redacted]	[redacted]
OY1 01-01-2013-12-31-2014	35	[redacted]	[redacted]
OY2 12-01-2014-12-31-2015	35	[redacted]	[redacted]
OY3 12-01-2015-12-31-2016	35	[redacted]	[redacted]
		Total Estimated Value	[redacted]

4. Statutory Authority Permitting Other than Full and Open Competition:

(X) (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1;
( ) (2) Unusual and Compelling Urgency per FAR 6.302-2;
( ) (3) Industrial Mobilization, Engineering, Developmental or Research Capability or Expert Services per FAR 6.302-3;
( ) (4) International Agreement per FAR 6.302-4
( ) (5) Authorized or Required by Statute FAR 6.302-5;
( ) (6) National Security per FAR 6.302-6;
( ) (7) Public Interest per FAR 6.302-7;

5. Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):

Both the American Society of Clinical Oncology (ASCO) and the National Comprehensive Cancer Network (NCCN) have included the Oncotype DX assay in their guidelines as an option to predict whether certain patients with breast cancer will benefit from chemotherapy.

The Oncotype DX assay may be used in newly diagnosed ER+, N- breast cancer patients to predict risk of recurrence. The assay can also be used to identify patients who may be successfully treated with tamoxifen and may not require adjuvant chemotherapy. Tamoxifen-treated patients with an excellent estimated prognosis may be spared adjuvant chemotherapy.

As a multi-gene diagnostic assay, the Oncotype DX assay is designed to support individualized treatment planning. The assay provides a quantitative assessment of the likelihood of chemotherapy benefit and distant recurrence, which may increase confidence that the treatment plan is tailored to the individual patient. Oncotype DX assigns a Recurrence Score from 0 to 100 based on the gene expression profile. Higher scores predict a great risk of recurrence and a greater likelihood of benefit from chemotherapy. Lower scores are associated with low risk and minimal chemotherapy benefit. Approximately one third of women with node negative and ER and/or PR positive tumors have been reassigned to a lower risk category and have been spared the expense and adverse effects of chemotherapy.

The Oncotype DX assay is performed in the licensed Genomic Health laboratory where the assay was developed. The Oncotype DX assay analyzes the expression of a panel of 21 genes from a tumor specimen using a technique called RT-PCR. The 21-gene panel assay was validated based on tumor recurrence score in a large, independent, multicenter clinical trial (NSABP Study B-14) and in a large population-based case-control study in breast cancer patients at Northern California Kaiser Permanente. The endpoints and analysis plan were prospectively defined.

No other vendor provides this type of gene-testing panel and no other breast cancer test has demonstrated the same levels of prognostic information for managing treatment of breast cancer.

This technology is considered proprietary to Genomic Health, Inc of Redwood City, CA. Genomic, Inc holds a patent for this test: US 7,056,674 for the Prediction of Likelihood of Cancer Recurrence.

6. Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:

A search in the Vetbiz registry under NAICS code 621511 revealed no matches to this NAICS code and key word "Oncotype".

These services are not available from GSA sources. The Federal Business Opportunities web site was also reviewed to identify other possible sources, however Genomic Health Inc. was the only source found. The Google search engine was also utilized to inquire of other possible comparable items. Per a telephone call to Ms. Karen Grogg on December 9, 2011, there are no authorized distributors for this test assay, and all service are performed at the laboratory in Redwood City, CA.

Market research will be conducted on a continual basis for new technologies that will provide the best value and the most benefit to the Veterans and VA Southwest Health Care Network's Laboratory Departments.

7. Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:

The established catalog price is currently [redacted] per patient; with a contract in place, the anticipated price will be [redacted] per test until March 1, 2012. This price includes the tests assays. As of March 2012 the price will convert to the then current Medicare Rate. Further price reductions will be sought. In accordance with FAR 15.402, the Contracting Officer has determined the estimated contract price is a fair and reasonable price. The total estimated price for services for the base period is $[redacted] and the base period plus three option years is [redacted]

8. Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:

Oncotype DX testing was developed by Genomic Health Inc., and they are the only company that can provide the testing. Oncotype DX testing is conducted using a technology patented to Genomic Heath Inc. that produces less of a variance in the test results versus other test in the market. Genomic Health does not have any other source in the country to perform their tests.

Previous acquisition information from the Phoenix VA Health Care System revealed this item was not available from any GSA sources. The using service and contracting activity has reviewed the current sources in GSA and could not find any comparable item our source. Federal Business Opportunities web site was reviewed and we found that many agencies have also entered into a Sole Source Acquisition with Genomic Health, Inc for the same required tests.

This technology is considered proprietary to Genomic Health, Inc of Redwood City, CA. Genomic, Inc hold s a patent for this test: US 7,056,674 for the Prediction of Likelihood of cancer recurrence.

As described in Section VI above, market research, in accordance with FAR Part 10, was conducted by synopsis of the proposed acquisition, advising industry of the pending acquisition and soliciting inquiries from interested parties.

On December 9, 2011, Ms. Karen Grogg, Contracts Manager with Genomic Health Inc. indicated that Genomic will process the assay at their site and no other laboratory around the country can perform the test, furthermore they do not have any authorized distributors. [redacted]

9. Any Other Facts Supporting the Use of Other than Full and Open Competition:

No other vendor provides this type of gene-testing panel and no other breast cancer test has demonstrated the same levels of prognostic information for managing treatment of breast cancer.

This technology is proprietary to Genomic Health, Inc of Redwood City, CA. The Prediction of Likelihood of Cancer Recurrence patent # US 7,056,674 to Genomic Health, Inc.

10. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:

Market research will be conducted on a continual basis for new technologies that will provide the best value and the most benefit to the Veterans and VA Southwest Health Care Network's Laboratory Departments.

11. A Statement of the Actions, if any, the Agency May Take to Remove or Overcome any Barriers to Competition before Making subsequent acquisitions for the supplies or services required:

Market research will be conducted on a continual basis for new technologies that will provide the best value and the most benefit to the Laboratory Departments at NMVAHCS, PVAHCS, and SAVAHCS. When another technology enters the commercial market place or when other vendors offer the same technology a competitive acquisition will be planned.

12. Requirements Certification: I certify that the requirement outlined in this justification is a Bona Fide Need of the Department of Veterans Affairs and that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge and belief.

12-5-11
Joann Silveri Date
Administrative Officer
New Mexico VA Health Care System
Albuquerque, NM

12/05/2011
Marita C. Stewart Date
Administrative Officer P&LMS, CS/113
Phoenix VA Health Care System
Phoenix, AZ

12/6/11
Ron B. Schifman, M.D. Date
Chief, Diagnostics
Southern Arizona VA Health Care System
Tucson, AZ

13. Approvals in accordance with FAR 6.304 a. Contracting Officer's Certification: (required) I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

12/6/2011
L. Danielle Provencio Date
Contracting Officer
V 18 NCO

b. **VISN/PCA QA:** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

VISN18 QA/COMPLIANCE PROCUREMENT ANALYST

REVIEWED
By VHAV18PereiP at 1:24 pm, 1/19/12

Paulette N. Pereira Date
QA Compliance Officer
V 18 NCO

c. **NCM/PCM :** I certify the justification meets requirements for other than full and open competition.

ACTING FOR:
1/23/2012
Sabrina J. Smith Date
Network/Program Contract Manager
V 18 NCO